Guide for Submitting Samples and Filling out the Chain of Custody

A Chain of Custody (CoC) is a legal document.
Failure to fill in a required field may result in a project being put on hold until information can be obtained and may result in a delay in sample processing. Fillable pdf is available for download on the Assured Bio USP<797> webpage.

Practices that Improve Sample Submission

- Submit smaller, clearly defined projects
- Use a unique project name
- Align physical sample label with the CoC sample identifier
- Seal media plates with parafilm
- Place all samples in a sealed plastic bag grouped by project
- Securely pack the samples with padding such as bubble wrap
- Multiple projects may be packaged in the same shipping container

CoC templates – create one digital template for each project type then edit relevant project information like name/initials, sample location, & dates. Create a template for:

- Semi-annual personnel competency
- Initial glove & garbing competency
- Monthly surface samples
- Air samples

Project Types

Personnel competency projects
Submit semiannual competency samples for each individual on a separate CoC with a unique project name - making competency records easy to retrieve, review, and document over time.

Example project names– include the name or initials of individual
Semi-annual Competency Testing J.Huong
JH - Semi-annual Competency Testing
Initial GFT Post Garb x 3 - J. Huong

Environmental Monitoring Projects
Separate monthly surface-monitoring samples and air-monitoring samples from personnel competency projects to maintain a clear distinction between environmental monitoring and personnel qualification records.

Example project names:
July 2026 Monthly Surface Samples - Laguna Bldg. 20 SCA
Monthly Surface Samples Laguna Bldg. 20 SCA - July 2026
Viable Air Samples Laguna Bldg. 20 SCA - July 2026

Chain of Custody fields - PAGE 1

*Facility / Pharmacy Name: facility/company name
*Facility / Pharmacy Address: mailing address, city, state, and zip code
*Primary Contact Name: primary contact for the facility who oversees USP<797> work; for correspondence, work orders, reports
*Primary Email for Report: primary contact email address
*Primary Phone Number: primary contact phone number
Secondary email(s): additional staff member(s) to receive work order and report. Contact the lab to set up a permanent list of secondary contacts or include on each CoC form.

*Project name / number: client's reference to the project or work involved with the samples
Sample Obtained By: name of the individual who collected the samples if different from the primary contact
*Collection Date: date samples were collected
Purchase Order #: client specific number to be listed on project invoice
Submission Type: select one option. "Other" can be further explained in "Customer Remarks/Special Instructions"

*Media Information: record the media type, manufacturer, lot number, and expiration date for each media type.
*Client-Supplied Controls: indicate whether positive and negative controls are included with the project.

Check "Shared Controls" when:
1) the included control is used for another project or
2) the control for the project was submitted with a different project.

*Identification Requirement: select the options that apply for the samples included in the project. If no identification is requested, check "none". Otherwise select "Action-Level Exceedance" for identification just for samples that fail the ISO action level or "Any Growth" for identification regardless of pass/fail status. Additionally, check the box for each applicable sample type.

Customer Remarks / Special Instructions: list special instructions about the project here, including other submitted project with the same control, additional isolate identification details, air sampler information, etcetera.

*Relinquished By: The name of the individual transferring custody of the samples. **Projects will be logged in under this name.**

Chain of Custody fields - PAGE 2 *Required

*Facility / Pharmacy Name & Project Name/Number: see page 1, fillable pdfs will auto-fill from page 1.

*Sample Identifier: The unique label applied to each sample by the facility. Used by lab staff to match physical samples to CoC details.

*ISO Class: Provide the classification from the International Organization for Standardization for each area monitored. Utilized to determine sample pass/fail.

*Sample Code**:** Fill in the sample code for the type of sample and desired analysis. Sample codes tell the laboratory how to process the sample and which USP <797> action-level criteria apply.

Single Plate Method**:** One sample is submitted and completes two incubation cycles (bacterial then fungal).
Dual Plate Method**:** Duplicate samples are submitted for the same location/technician. Both plates begin incubation at the same time; one duplicate at 20-25° and the other at 30-35°.

- Environmental Monitoring: monthly surface and viable air samples
- Personnel Competency: initial and semiannual competency testing
- Garbing & Glove Hygiene: gloved fingertip sample collected after donning lab coat and gloves and before media-fill testing
- Aseptic Manipulation: sample collected after aseptically preparing a media-fill sample (IV bag, vial, syringe)

*Location / Description**:** Utilize this field to record the sampling room/item, Haz or Non-Haz, Dynamic vs Static, number of people in the room, etcetera.

Total Volume/Area: Only applicable to surface and air samples. Record the total volume of air samples in liters (L) and the total surface area sampled in square centimeters (cm^2). Air sampler details can be left in the customer remark field for your records but are not included in the report.

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